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PATENT

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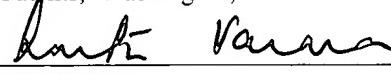
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: McKeon et al.)
Serial No: 09/538,106) Group Art Unit: 1642
Filed: March 29, 2000) Examiner: A. Holleran
Title: Cell Regulatory Genes, Encoded Proteins)
And Uses Related There to)

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231.

Date of Signature: August 3, 2001
and of Mail Deposit


Anita Varma

Commissioner for Patents
Washington, D.C. 20231

Sir:

RESPONSE TO RESTRICTION REQUIREMENT

In response to the Restriction Requirement dated July 3, 2001, Applicants provisionally elect with traverse the invention set forth in Group III, claims 2-10, 13 and 14. In addition, Applicants provisionally elect with traverse "the detection of a polypeptide encoded by a nucleic acid sequence which hybridizes to SEQ ID No: 6 or detection thereof."

In the restriction requirement under 35 U.S.C. § 121, the Examiner alleges that there are three distinct inventions as follows:

- I. Claim 1, drawn to a nucleic acid sequence encoding a p63 cell regulatory protein, classified in class 536, subclass 23.5.
- II. Claims 2-10, 11 and 12 drawn to methods for diagnosing malignant carcinoma, detecting onset of cancer, or distinguishing cervical squamous carcinoma, to the extent the methods read on determining the level of a p63 gene product that is a

nucleic acid product, classified in classes 435 and 536, subclasses 6 and 24.3, respectively.

- III. Claims 2-10, 13 and 14 drawn to methods for diagnosing malignant carcinoma, detecting onset of cancer, or distinguishing cervical squamous carcinoma, to the extent the methods read on determining the level of a p63 gene product that is a protein product, classified in classes 435 and 530, subclasses 7.1 and 387.1, respectively.

According to the Examiner, “According to the Examiner, “these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate status in the art as shown by their different classification, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.”

Applicants respectfully traverse this restriction. The Examiner’s attention is directed to M.P.E.P. § 803, which states that: “If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.” Thus, for a restriction requirement to be valid, the Examiner must establish the following two criteria:

- (1) the existence of independent and distinct inventions (35 U.S.C. § 121); and
- (2) that the search and examination of the entire application cannot be made without serious burden (M.P.E.P. § 803).

Applicants respectfully submit that the Examiner has not shown that the second requirement has been met, particularly with respect to Groups II and III above. In particular, Applicants note that each of these Groups is classified in class 435, meaning that a search of one Group would overlap significantly with a search of the other groups. Therefore, it is Applicant’s position that the restriction requirement is in error and that the Examiner has not shown that a serious burden would be required to examine all the claims.

Further, Applicants traverse the election of species/restriction requirement that has been imposed in this case, for the following reasons:

- a. Applicants respectfully submit that the Examiner has failed to provide the legal basis for this requirement. It is unclear whether this is an election of species or a restriction

requirement. The pending claims have already been restricted into three distinct groups. The Examiner characterizes the claims as constituting an “implied, misjoined Markush group.” The Examiner then states that “upon election of either group I or II, Applicant is additionally required to *elect a single species* from the following groups . . . (*emphasis added*)” [Page 3 of the Office Action dated July 3, 2001.] The Examiner further states: This requirement is *not to be construed as a requirement for an election of species*, since each of the polynucleotides recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention (*emphasis added*). [Page 4 of the Office Action dated July 3, 2001.] Applicants request clarification of these inconsistencies.

b. Applicants respectfully submit that claim 2 is not dependent upon claim 1 and claim 2 and the subsequent method claims do not contain the language recited by the Examiner, i.e., “a protein encoded by a nucleic acid which hybridizes to SEQ ID NO: 1 or detection thereof . . .” However, Applicants have provisionally elected a species as “characterized” by the Examiner.

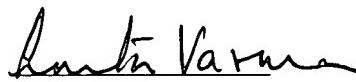
c. As discussed above, according to the Examiner the claims constitute a “implied, misjoined Markush group.” The MPEP clearly sets forth the restriction practice to be followed with respect to Markush claims. In particular, Section 803.02 of the MPEP specifically states that “if the members of the Markush Group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without a serious burden, the Examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions. (*emphasis added*)” In this case, the members of the Markush Group are sufficiently few in number and each sequence represents an isoform of the p63 polypeptide. Accordingly, Applicants respectfully submit that Applicants are legally entitled to a search and examination of all members of the Group as set forth by the Examiner.

If there are any other fees due in connection with the filing of this Restriction Requirement, please charge the fees to our **Deposit Account No. 06-1448**.

If there are any questions regarding the filing of this document, the Examiner is invited to contact the undersigned Attorney at (617) 832-1242.

Respectfully submitted,
FOLEY, HOAG, & ELIOT

August 3, 2001



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